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Papers of N.C.A. Representatives at the 12th Annual Meeting of the Institute of Food Technologists

Representatives of the National Canners Association delivered technical papers at the 12th annual meeting of the Institute of Food Technologists, held in Grand Rapids, Mich., June 8-12.

H. Thomas Austern, Chief Counsel of N. C. A., was asked to present the legal background of the current proposals for new legislation on food additives. His paper was entitled, "The Legal Framework for Proposed Legislation Controlling Possibly Toxic Food Ingredients."

E.S. Doyle of the N.C.A. Western Branch Laboratory spoke on "Your Own Inspection System for Better Sanitation." (page 11).

Because of the nature of these papers and the widespread interest among canners in the subjects of discussion, these papers are reproduced here, with the permission of the Institute of Food Technologists.

The Legal Framework for Proposed Legislation Controlling Possibly Toxic Food Ingredients

By H. Thomas Austern,
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Perhaps in historical perspective the key question of these middle decades may well have been whether scientifically trained men courageously met the challenge of the world that they so drastically changed.

All around us the kind of life we lead, and certainly its tempo, reflect the growing application of constantly expanding scientific research. Whether these developments – in transportation, in chemistry, in bacteriology, in medicine, in electronics, and in almost every physical science – will eventually result in a more abiding and abundant world, or in its devastation and dramatic destruction, turns on political decisions whose resolution demands the alert and knowledgeable attention of each of you.

The Scientist's Responsibility

For in a democracy scientists cannot evade their responsibility as citizens. Indeed, where the political decision demands an understanding of technical potentialities and hazards, it is perhaps the required task of the scientist to take the lead in public discussion.

Not since 1946 has a greater challenge been presented to a particular group of technologists to apply their specialized knowledge in reaching a sound political judgment on an emergent problem. In that year, you may recall, the physicists who had developed the atomic bomb awakened to their responsibilities as

citizens in helping to shape the future Governmental control of atomic energy. Despite the tradition that American scientists do not meddle in politics, as James Newman recounts, (1) they

> "swarmed down from their ivory towers, and with energy, fervor, passionate conviction, and a somewhat unexpected talent for organization"

told Congress what they thought about military versus civilian control of fissionable materials, about nucleonic research, patents, and the security control of scientific inquiry.

In perhaps a more limited -- but hardly less important -- area of public concern, food technologists today are challenged to concern themselves with political issues that are admittedly controversial but which insistently demand study by those uniquely competent.

The Problem

These issues concern what has been called the "chemical additive" problem. Along with Commissioner Crawford, (2) I think that characterization is a misnomer. Nor are the labels "new chemicals" or "dangerous chemicals" any less inept.

For the area you must explore is not confined by semantics. It extends over the boundless reaches of research and technical application occupied by all of the men and women attending this annual meeting of the Institute. Since the underlying pattern runs through the fabric of your daily jobs, I need not catalog the familiar. Indeed, the background is now almost common knowledge. (3)

With the development of centralized production -- and to some extent the mass production -- of food products has come the scientific reexamination of the purpose and functioning of many food ingredients. There has also been a consequent progress in the improvement of food products. As a familiar example, the addition of small quantities of calcium salts to canned tomatoes has given the consumer a more useful product.

Similarly, the development of organic pesticides has permitted the bringing to harvest of better and more abundant fruits and vegetables. (4) The introduction of anti-oxidants, of emulsifiers, of coagulants, and of various inhibitory agents has often afforded the consumer not only a more palatable product but also a more economical one through the elimination of waste or other household loss.

Yet not all changes are improvements. The substitution of one ingredient for another may result only in a concealed cheapening or debasement of the food. Even where lower food values are not wholly involved, the new ingredient may challenge the economic position of existing suppliers -- as the controversies about oleomargarine, diglyceride shortening, and surface active ingredients have demonstrated. But vitally important -- and unrelated to economics -- is the threat to the public health in the continuous ingestion, even at low levels, of new ingredients which may turn out to be chronically toxic.

Since most of the new developments in the growing or processing of foods involve the use of highly refined or newly synthesized substances, this public health problem is popularly and Congressionally-termed "chemicals in food products," or the use of "chemical additives." I prefer the original concept of a "poisonous or deleterious" ingredient which is the language used in the Act, or perhaps even the simpler term, "unrecognized food additive."

Perhaps, too, you will agree that it serves no useful purpose to attempt, as many do, to draw a distinction between "natural" and "unnatural" food ingredients. The eating of grasshoppers may be natural to some and repulsive to others. There was a time, we are told, when the tomato was regarded as poisonous.

Moreover, there is no real basis for assuming that everything we are now accustomed to eating is necessarily wholesome. As a witness before the Delaney Committee suggested:

> "From the point of view of chronic toxicity of foodstuffs, the centuries-old experience of mankind does not have as much value as appears at first sight. Who knows that some common diets do not contain cancer-producing agents? Who knows that if we could eliminate certain foodstuffs from the diet we would not considerably lessen the incidence of diseases of the blood vessels, of the liver, and of cancer? If nutritionists had the time, facilities, and the inclination to study such problems, it would be interesting to feed rats, for their

life span, a large number of staple food articles which are now considered completely innocuous." (5)

Fortunately, our present problem is not as vast. It does not encompass either a legislative or administrative reexamination of the worth or hazard of eating familiar foods. It does not contemplate legal evaluation of either a vegetarian or carnivorous diet.

The Legal Question

Instead, it concerns but a single issue: If any new ingredient is developed for food use – if in the production or processing of any food product any new substance may be inadvertently added or intentionally introduced -- how is the danger of possible chronic toxicity to be controlled?

The specific legal problem is perhaps even narrower. For at least the past forty years, and longer in Canada, it has been generally recognized that it is an appropriate function of Government to prohibit the addition to food products of ingredients that are poisonous or deleterious. The basic rule, clearly reiterated by Congress in 1938, is that the unnecessary addition of poisons to any food should be absolutely prohibited. (6) No poisonous substance may be added or employed except where its use at levels which will not endanger the public health is unavoidable. Likewise, no one suggests that the use of any new food ingredient, or of any new pesticide that may leave a detectable residue, should not be preceded by adequate inquiry as to its possible toxicity. As far as I know, no one has advanced the notion that anyone may, with impunity, utilize human beings as guinea pigs without their knowledge and consent.

The current question is therefore not whether the government should prohibit the use of a potentially dangerous food ingredient or the retention of toxic residues beyond a demonstrably safe level. The argument concerns the manner and mode of prohibition – whether there should be freedom to utilize any ingredient subject to prosecution if it should turn out to be harmful, or whether the use of a new ingredient should be barred until its safety is predetermined by some agency of the government. As an inescapable corollary, it is necessary to decide who should have final authority to determine this question of danger to the public health -- a court or a jury, an advisory panel, or an administrative agency?

Elsewhere I have reviewed the series of events following World War II that brought these questions into acute focus and led to the Delaney Committee hearings which have run from June 1950 to last month. (7) In addition to the printed transcript of these hearings -- which belongs in the library of every food technologist -- there is now also available to each of you a large bibliography replete with discussions of the many aspects of this problem in scientific, legal, sometimes objective, and often polemical terms.

My assignment this afternoon is briefly to suggest some legal background that may, it is hoped, illuminate your individual consideration. In this endeavor, I speak for no group or particular point of view, and offer no definitive answers.

Objectivity is no easy effort – particularly for a professional advocate. Inevitably, one who attempts, midst a storm of controversy, to navigate between the Scylla of passionate conviction and the Charybdis of aloof neutrality may find himself becalmed in indecision. Even if a hoped-for lack of bias often puts one in the position of the sparrow who wandered into an active game of badminton, complete objectivity remains my goal this afternoon.

Questions for Congress

When the new Congress meets next January it will be asked to answer two questions that each of you ought to resolve for yourselves.

First, is there any need for new legislation to control further the inadvertent or intentional addition to foods of possibly toxic ingredients?

Second, if new legislation is needed, what form should it take to avoid what the Delaney Committee has termed "unnecessary obstacles to technological improvements in food production and processing"? (8)

No one builds a new wing to his house without determining how it will supplement and connect with the existing structure. Necessarily, the first task is to examine how the present law operates. Evaluation of the efficacy of both the existing law and of any new proposal may, however, be helpfully illuminated against the background of some basic legal principles implicit in our system of government.

Basic Concepts

Fundamentally, the issue of abstract freedom versus systems of prior approval runs all through the law. In the Anglo-American common law, the basic idea is that ordinarily a man may act without first getting governmental permission, but is always responsible civilly and criminally for any wrongful conduct. The injunction -- the legal inhibition against specific action -- is unusual. Prior restraint on particular individual conduct is the legal oddity, difficult to secure, and obtainable only where irreparable injury is clearly threatened. For example, a man may be acutely injured by an unfounded libel or slander. Yet our interest in free speech is so strong that prior restraint on any publication or the opportunity to talk is constitutionally prohibited.

The past half-century, however, has seen the growth of what lawyers call preventive law These are regulatory systems under which a man cannot act without first getting governmental permission, and is legally protected if he does not exceed the permission granted.

This technique of government has derived momentum from two sources. Primarily, restriction on freedom of action without government permit has been invoked in situations where the protection of the public is deemed paramount. You cannot dig a ditch in a public street -- in most states you cannot drive an automobile, you cannot practice medicine or law, you cannot sell alcoholic liquors -- without first obtaining authorization.

In addition, systems of advance scrutiny have developed in many areas because those who had to act did not care to hazard the responsibility for error. Out of this has come such things as government certification of the grades of food products, the obtaining of tax rulings, and other authorizations sought not primarily for public need but for private advance assurance of legal propriety.

Over-all, however, our American law still is strongly biased toward freedom of action. We do not tolerate censorship of speech or print except in time of war and then largely in combat areas. Recently the Supreme Court has said that you cannot ban the showing of a motion picture on the ground that it is "sacrilegious." The number of businesses in which a man may not engage without prior license is relatively few.

Of course, when there are overriding interests of public health, safety or morals, interference with freedom of action can be extreme. Dangerous psychotics are incarcerated. The possession of narcotics is made presumptively illegal. No one may work on a defense project without security clearance. Despite the sanctity of free speech, permits can be required for public meetings or the distribution of commercial handbills or peddling in the public streets.

Moreover, in most instances the law has always retained the ultimate responsibility of the individual for any wrongdoing. Though one may not sell stock without an S. E. C. registration, he still remains responsible for misrepresentation in his prospectus. Though you may be licensed to drive an automobile, you still can be fined for speeding or sued if you damage another's property. Government certified coal tar colors may be employed in a food product, but still they may not be used to conceal inferiority.

Controlling Criteria

This all may sound like lofty jurisprudence -- remote from the present problem -- but in an important sense it is of the essence of democracy. In any political judgment as to the desirability of legislating that a man may not act without prior Government approval, we always start with the assumption that freedom of action is good and regulation unwarranted except to the extent vital to the public interest. That determination in any area of public control always requires three inquiries.

The first is a realistic appraisal of the degree of danger -- absent prior restraint -- to the public health, morals or safety if private action is permitted. Another way of viewing this point is to consider whether the threat of later punishment for wrongful action is a sufficient deterrent to conduct that may work a major public injury.

The second task is to evaluate the harm which a system of prior restraint may inescapably cause. Wholly apart from our instinctive bias toward freedom, experience also teaches that every governmental permit system causes some delay. Of course this may not always be a bad thing, as the three-day waiting period for marriage licenses has sometimes demonstrated. But even where speed must yield to safety, it is generally admitted that prior restraints do result in some loss of initiative -- in the impeding effect of disclosure

of program -- and in loss of momentum on new projects.

Moreover, in any system of prior restraints there is some denial of choice. The parent who feels that his boy is qualified to drive at fourteen loses the choice to have him do so because of the potential danger to the public in all children of that age being allowed to drive.

Third, in considering any proposed system of prior restraint, any competent legislator must examine the difficulties of administration -- whether workable standards can be evolved to preclude arbitrary denial -- the practicability of a permit system -- and necessarily its cost.

Properly to balance these diverse interests is never an easy task. Doing so in any area of government requires full information, an alert and manifested public expression to which Congress may respond, and immeasurable wisdom. Where the need for new legislation is grounded on protection of the public health, a sound and dispassionate judgment is even more difficult.

A full examination of the varied ways in which Congress, in the Food, Drug and Cosmetic Act of 1938, resolved this basic question -- freedom of action risking the penalties of wrongful conduct as against prohibiting action without prior administrative permission -- is beyond the scope of my assignment. Generally speaking, nowhere in the food sections of the law is there any requirement that day-to-day food production cannot be carried on without prior explicit or detailed administrative authorization.

Of course, there are provisions for official regulations. But by and large these are directed toward permitting exemptions from specific prohibitions. Except for the emergency permit control section (Sec. 404) -- which in terms is an emergency section and rarely if ever utilized -- food manufacturers remain free to act without first securing Government permission. If they violate the law, they may be punished by fine, imprisonment, and the condemnation of their goods. But they do not have to obtain permits or licenses in order to conduct their operations.

Deleterious Ingredients Now Prohibited

Insofar as poisonous or deleterious ingredients are concerned, the law in Section 402(a)(1) specifically prohibits the addition to any food of any poisonous or deleterious substance "which may render it injurious to health." This is the basic prohibition against the use of any added poisonous or deleterious substance. The statutory text is unequivocal, and both it and the legislative history make it clear that Congress intended that no ingredient could lawfully be included -- whether inadvertently or intentionally -- in any food where that addition might render it a danger to public health.

As I hope I have by now made clear, however, this prohibition operates completely after the fact. Anyone may add any ingredient to any food product, and anyone may sell a product containing any poisonous residue, if he is satisfied that -- or even if he does not bother to inquire whether -- the particular level of use is noninjurious. It is up to the government to establish in its prosecution or seizure both that the added ingredient or residue is "poisonous or deleterious" and that at the particular level of use it may injure health. This is a substantial burden of proof, and in a criminal case must be beyond a reasonable doubt.

Congress did, however, in 1938 additionally recognize that in the case of pesticides some balance would have to be administratively fixed between the necessary use of certain admittedly poisonous pesticides and the protection of the public health. This process is familiarly known as the establishment of residue tolerances.

Congress did so by independently providing in Section 402(a)(2) -- and its corollary Section 406 -- that if any poisonous or deleterious substance were added to any food -- and the FDA found that its addition was required in the production of that food, or could not be avoided by "good manufacturing practices" -- its employment would be lawful. Only where the FDA had so determined in a proceeding under Section 406 that its use was required and unavoidable -- and established permitted tolerances -- could the added poisonous ingredient supposedly escape the basic prohibition.

Except for one unsatisfactory attempt to control spray residue levels on apples, it was not until 1949 that comprehensive hearings were scheduled on pesticides. These were concluded about a year ago, and it is anticipated that permitted residue levels for fresh fruits and vegetables may soon be issued.

Absent a tolerance under Section 406, following a hearing in which toxicity is examined, the only legal

deterrent is possible FDA action under Section 402 (a) (1) after the product is shipped. We have already seen that to support a seizure or prosecution under that Section, the government has to establish both that the added ingredient is poisonous or deleterious and that as used it is injurious to health. Except in extreme cases, such as the use of a fluoride as a preservative in beer, this has been a difficult task.

Nor has the burden been lessened in those cases where clear evidence either of poisonous character or of complete safety is lacking. Necessarily, prosecution could be undertaken only after some data as to acute or chronic toxicity was secured, and apprehension existed as to whether the limited number of FDA personnel and its modest budget could ever keep up with the expanded use of new chemical ingredients and the difficulties of their detection.

For it cannot be denied that there is nothing in the present law which requires advance approval of any ingredient sold and shipped for incorporation in a food product, or the advance approval of the sale of any food product incorporating that ingredient, even where it can readily be demonstrated that the ingredient is poisonous or that nobody knows whether it is or is not poisonous.

This is not to say that every newly developed ingredient is toxic. Admittedly, most of them are not. Suppliers in many instances, and extensively in the pesticide field, have made their own investigations of acute and chronic toxicity. Others have informally cleared with the FDA the proposed introduction of new ingredients.

Effect of Standardization

Of course, whenever a food came to be standardized, the permitted use of every ingredient came into question. If doubt existed as to its wholesomeness, evidence on this point was taken. Yet this procedure was believed to be both too burdensome and too late. Often the testimony and argument about the toxicity of minor ingredients overshadowed the rest of the standard hearing, and imposed a real burden in time and cost upon those not overly interested in their use.

Inevitably, the more widely an ingredient had come to be commercially employed, the stronger would have to be the showing of its deleterious potentialities before it could be outlawed. By the same token, even a convincing demonstration of danger to the public health would come only after very considerable actual usage.

Yet in a good number of instances many new substances were widely marketed and their use only later brought to light in standard-making proceedings. The fear exists -- deeply felt by many and considered exaggerated by some -- that error might mean, not necessarily a dramatic series of deaths from acute poisoning, but widespread public injury through the ingestion over long periods of time of materials of chronic or cumulative toxicity.

Against this background, food technologists must consider the cardinal problem as to whether any real need exists for further legislation. The law is explicit in prohibiting, and punishing after the fact, the unnecessary addition of any poisonous or deleterious ingredient. Machinery is provided for evaluating -- necessarily in prolonged and arduous administrative proceedings -- whether the use of admittedly toxic substances are necessary for production and what tolerance constitutes a proper accommodation of that need to the protection of the public health.

The food manufacturer who transgresses these lines is subject to criminal prosecution, to fine and imprisonment, and to the seizure of his goods. But one who ventures to sell a new ingredient or to incorporate it into a food -- either in the mistaken belief that it is not toxic, or without caring whether it is -- remains free to hazard these penalties. Admittedly in close cases there are inescapable difficulties of policing and successful prosecution.

Existing Points of View

Whether the asserted danger to the public health is sufficiently real and imminent to warrant a permit system for newly developed food ingredients, whose safety is not generally recognized, is presently a controversial question. On the basis of its 1950 hearings the Delaney Committee concluded that the present law is inadequate and that it should be amended to provide for the prior administrative clearance of any "chemical additive."

It would indeed be surprising if the Committee's final report did not take the same view for which it can find a great deal of well-qualified support in its later hearings. The Food and Drug Administration

likewise urges the need for prior administrative clearance of new ingredients not generally recognized as safe.

Others insist that the apprehensions voiced are exaggerated; that no demonstrated case of public injury has been made; and that the price the food industry and the country would have to pay for a permit system is too high because it would thwart the development of better foods, stifle initiative in further research, and lay the dead hand of bureaucracy on progress.

As I have noted, no one insists upon absolute freedom to incorporate admittedly toxic substances. No one challenges that the introduction and use of a new ingredient requires pretesting as to its possible chronic toxicity. Indeed, almost everyone admits that advance notice to the Food and Drug Administration of the use of a new and unrecognized ingredient, together with all available information concerning it, would be a desirable improvement. The battle lines are drawn at the point as to whether any use of a new ingredient may be made until there is Governmental clearance and specific authorization. Even among those who subscribe to the idea of required prior approval, there are further differences as to whether the Food and Drug Administration, an independent advisory panel of experts, or the courts shall have the final say as to whether any new substance has been adequately tested to determine its possible toxicity, or where it is admittedly poisonous whether its use is necessary and, if so, will or will not at a particular level endanger the public health.

In short, there appears to be considerable, though hardly universal, agreement that the present law can be improved. The real area of conflict is as to means and methods.

The proposals for new legislation up to this time fall into three categories:

First, required specific prior clearance;

Second, required advance notice of use; and

Third, a combination of required advance notice and an opportunity for immediate court prohibition where toxicity is questioned or unknown.

The Miller Bill

The first is that of the Delaney Committee and the Food and Drug Administration originally embodied in the Miller Bill, H. R. 3257. This follows the pattern of the new "drug" section of the law. Elsewhere I have attempted a detailed analysis of the Miller Bill. (9) It suffers, in my opinion as a lawyer, from some now admitted deficiencies in drafting. (7) Basically, the Miller Bill specifies that before any substance -- not generally recognized by qualified experts as having been adequately tested to show that it is not poisonous or deleterious -- may be sold in interstate commerce, an application must be filed, giving complete information as to composition, toxicological investigations, methods of analysis, recommendations for use, and if offered as a poisonous pesticide required in the production of food, all information as to resulting residues. The definition of "substance" is very wide and embraces all pesticides, additives, or even packaging materials likely to contaminate a food product.

Within 60 days the Administrator must act on the application. He may refuse authorization if he finds that there has been inadequate testing as to toxicity, or that the proposed ingredient is poisonous or deleterious, or that the methods of analysis are inadequate or inaccurate, or that on the basis of all of the information he simply cannot determine whether the proposed ingredient is or is not deleterious.

As Commissioner Crawford has pointed out, (2) certification under this proposal will not automatically afford a green light for all food usages. A new ingredient, even if found to be wholesome, may not be employed in any way to achieve adulteration. Its use will have to run the gamut of all of the adulteration and misbranding prohibitions of the Act. For example, where a standard of identity controls what may be the ingredients of a food product, amendment of the standard would be necessary before even a certified new ingredient could be added to that food. Certification will merely clear the hurdle of the new amendment requiring prior application and approval preceding any food use of new ingredients not generally recognized as safe.

Even those who support this proposal in principle are not thoroughly in agreement on certain supplementary but important issues. The key one is whether the final authority to determine these intrinsically difficult toxicological questions shall reside in the Food and Drug Administration. Among the arguments

made is the apprehension that the awesome responsibility for clearance may lead to administrative timidity, to delay, or to use of the readily available escape hatch of finding insufficient information on which to approve.

One proposal is to supplement the FDA in this area with an Advisory Council. This Council would consist of five people appointed by the Public Health Service and would include one representative from that Service, the Food and Drug Administration, the food industry, the chemical industry, and an outstanding pharmacologist. If the Food and Drug Administration concludes that a proposed new ingredient cannot be approved, the application and the record would go to the Council who would then serve as an appellate court whose decision would be binding on the FDA.

Another approach to this problem of finality would be to throw it into the courts. The Miller Bill follows the general pattern of permitting an appeal to an appellate court and further specifying that all findings of the FDA shall be conclusive if supported by substantial evidence. The objection is made, and is I think well founded, that under this directive an appellate court will be extremely loath to second-guess the Food and Drug Administration on a question of public health. Hence the suggestion is that review be had in the Federal District Courts where there would be what lawyers call a trial de novo. The entire application would be open and all issues of fact would be retried, and presumably a Federal judge and possibly a jury would render a profound legal-medical judgment subject to further scientific review by the appellate courts.

The Advance Notice Proposal

The principal alternative to the Miller Bill is the proposal for advance notice. This is necessarily responsive to the present FDA complaint that new food ingredients occasionally are employed and not detected until much later. It rests, however, upon a judgment that the price which the food industry would pay for a system of prior clearance is not warranted by the disclosed need.

In general, the alternate proposal is that no food manufacturer may sell any product containing a new "food additive" unless and until he has filed a notice of his intention to use it. That notice must contain a statement of composition, full reports of investigations on toxicity, methods of analysis, samples, and all directions for use including maximum amounts in terms of ppm. The notice must be filed 60 days prior to the shipment in interstate commerce of any food product containing the new ingredient.

Obviously the theory behind this advance notice proposal is that when it is furnished with all available information, the FDA can conclude within the 60 days whether the product is poisonous or deleterious in that it may be "injurious to health" under the present law, and either prosecute, seize, or seek an injunction. I suppose that practically, if the FDA announced its intention to do so, this alone would be a considerable deterrent effect. Likewise, it would have the same difficulties of prosecution now encountered except that it would be far better armed. The same concept of a trial de novo in the courts would prevail.

Nor is it as yet clear what the FDA would be authorized to do if the data furnished in the advance notice was insufficient to enable any fair-minded and realistic toxicologist to come to any conclusions. There is a suggestion that where this situation exists, the FDA may summon those who filed the notice to a conference.

Yet to some this proposed legislative silence may eloquently bespeak some basic fears. These perhaps reside in areas of apprehension not too often frankly expounded: Where insufficient data permits a negative official answer, a prejudiced man can always insist on more and more data; since here, as in most situations, certainty is always relative, even the unprejudiced may demand the impossible in terms of demonstration; and where official sanction may mean immediate and possibly wide usage, there is always available to the timid what I have already called the escape hatch of authorized indecision.

The Notice and Injunction Proposal

Finally, there has been a proposal to combine this advance notice idea with the opportunity for the Food and Drug Administration immediately to seek an injunction on the ground that the announced use of the new ingredient would jeopardize the public health. The real difference between the second and third proposals is that under the advance notice concept the FDA might be required to prove that the proposed new ingredient was in fact poisonous or deleterious to the point that it might be injurious to health, and under this modification it presumably could obtain an injunction on the ground that the information furnished was inadequate or inconclusive on this issue.

There are some lawyers who doubt whether in any practical context this is a real difference. They believe that it would be a rare case where a judge or jury would permit the use of a new ingredient in the face of an FDA insistence, however phrased, that such use might injure the public health. True, the proposal eliminates the problem of the "negative finding" -- that a substance is to be prohibited because it cannot be shown to be safe. But it does so by seemingly recognizing that in this particular area a reasonably demonstrated failure to establish lack of toxicity is a sufficient basis for foreclosing use.

The real issue buried in these legal arguments about finality lies, in my opinion, less in what the courts may do, and more in what any variant of the trial de novo will lead the administrative officials initially to do. If the only thing for court review is a carefully articulated administrative finding -- sometimes safely encased in the precisely controlling words of the law itself -- with that finding considered conclusive unless plainly arbitrary and capricious -- the public burden on the administrative officer is not onerous. If, on the other hand, those in the FDA who make the toxicological judgments must appear in court and present the facts and conclusions on which they desire to exclude, and more important stand cross-examination, there will probably be more rigid requirements and perhaps a fuller articulation in support of the administrative determination. At the least there is the practical difference that in one instance a negative administrative finding suffices to foreclose use, in the other it is necessary for the FDA to bring a legal proceeding.

By the same token there will undoubtedly be a greater burden upon the FDA. I am confident that every court appearance of a food and drug official on one application will necessarily mean a delay in processing others. In the long run any conclusion on this issue may turn on one's confidence in the thoroughness, objectivity, and impartiality of the administrative determination absent the possibility of later public and detailed court exposure. Often this question is posed only indirectly in terms of the usually polite objection that, "the splendid fellows now in the FDA may tomorrow be replaced by others far less competent or fair."

Where you will come out in your own resolution of these pressing questions must turn on your own evaluation of the facts. Many qualified men insist that there is a definite need for new legislation. They are joined by Food and Drug officials, at least some of whom are already sufficiently burdened as not chargeable with seeking additional authority for the sake of power alone. The Delaney Committee undoubtedly will reach the same conclusion.

Ultimate Judgment Is Not Legal

Whether the danger to the public health can be adequately met by an advance notice type of amendment -- or whether nothing short of required prior specific clearance will suffice -- will depend upon Congressional evaluation of the many subsidiary arguments, some unfortunately semantic, some residing largely in personal experience or predilection, and others perhaps wholly imponderable. I am satisfied that none of the basic judgments is ultimately legal and that none is beyond the competence of an informed food technologist. All of the pros and cons are by now fully available to you in the published materials. The necessary judgment is political in the best sense of that term.

If you fear that the requirement of a prior application and specific FDA clearance will, in the words of one technologist, "result in loss of industry-incentives to support research, will decrease the amount of research, will lower the morale of research personnel and will progressively reduce the rate of progress in the food industry," (10) your political orientation will presumably be affected despite the contrary record of the "new drug" section. (11)

If you read the Delaney Committee hearings to mean that the burden of proving absence of chronic toxicity may be made so formidable as to be unattainable -- necessarily encompassing in the words of one Food and Drug finding consumption "continuously over a life span" of a human being, (12) or at least two reproductive cycles of a goat -- these apprehensions may become magnified.

If, as one analyst of this problem has suggested, the margin of safety on toxicological inquiry "is in reality a margin of uncertainty" -- and legal findings of fact in this area are merely a scientific poetic license (13) -- you may share the fears of those who foresee arbitrary action and the impeding impact of official apprehension if not ineptitude.

If, on the other hand, you are persuaded that there is real need for further control -- that administrative officers are after all human beings cognizant of their

limitations — and that common sense must, as everywhere else, remain the touchstone of good administration — you may conclude that the need for protecting the public health by requiring the full remedy of prior administrative clearance is worth whatever the feared or actual price may turn out to be.

On only one point do I venture certitude. The responsibility for investigating these questions lies not only with Congressional committees. It is not the sole prerogative of government officials. Nor by any stretch of the imagination is it within the exclusive competence or capacity of lawyers. In a real sense every food technologist must be prepared to answer as a citizen. For primarily now under political scrutiny are your research, your resource and ingenuity, your technical skill, and fundamentally whether your activities in the future will foster or may endanger the public welfare.

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Your Own Inspection System for Better Sanitation

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Sanitation is sometimes regarded as "a thing apart," something "abstract" -- or like "religion only on Sunday." This is most short-sighted and anyone who has this feeling about sanitation is heading for trouble. The trouble may be with regulatory officials but it may also be internal problems with production and quality that a well-operated sanitation program in the plant could have prevented. Sanitation is an integral part of food processing and should be recognized as such.

The ultimate objective of every food processing business is to produce a marketable product and sell to consumers in competition with other products. Ordinarily consumers do not have the opportunity to inspect plants or to express desires to the plant managers except through selective buying and through the food sanitation laws passed by their elected representatives. However, these are both potent forces to which any organization must give careful consideration. These laws and the enforcement of them are in the interest of the consumer and the farsighted manager realizes they are therefore in the interest of the industry although compliance may be difficult for some individuals. That such laws are good for industry was recognized a long time ago and the food industry as a whole actively supported the enactment of the basic Food, Drug and Cosmetic Act.

This act specifies that food containing filth (anything objectionable to a discriminating consumer) is adulterated and subject to seizure. In addition, food is adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth. In other words, the product is considered adulterated if the production environment, the plant, is not clean, free of rodents, insects, etc., regardless of demonstrable filth in the product. Product adulteration or an insanitary production environment not only makes the product liable to seizure but the company can be fined as well. The manager, as the person ultimately responsible for all activity, and other responsible members of the organization, can be held personally liable and are subject to fine and imprisonment even though they may not be aware that violations of the sanitation regulations exist in their plant. (1)

Trichter (2) states that during 1950, in New York City some 78,000 violations were placed on about 14,000 wholesale and manufacturing food plants by the New York City Health Department. Some idea of the expenditures necessary to correct some of these violations can be obtained from the few cases he describes.

A milk plant had to spend $50,000 to replace a leaking defective vat pasteurizing system.

A candy manufacturer had to build and equip a new building at a cost of $150,000 to eliminate an insanitary hand-dipping operation.

Another plant spent $6,000 to provide sinks, chutes, hand trucks, covers, hoods, etc. which were of sanitary construction. Water supply lines had to be replaced, floors regraded and walls waterproofed.

A coffee roaster spent $15,000 to eliminate a smoke, odor and chaff violation.

An ice cream manufacturer spent $75,000 to replace rough brick with tile walls and relocate a toilet so as to provide more space for cleaning.

It cost $30,000 to eliminate an odor nuisance in a fish dehydrating plant.

These may not be representative examples but there must be many thousands of dollars spent each year to correct objectionable sanitary conditions. Too often management doesn't give sanitation serious enough consideration until there is trouble and then they hire a sanitation expert to get them out of the mess. This is usually expensive whereas the trouble might have been prevented earlier at little or no added cost. Insanitation is preventable, but we cannot expect government inspectors to prevent insanitary practices before they occur. Although they work in this direction as much as they can, the laws, the enforcement of which is their responsibility, do not make provisions for prosecuting before a poor condition occurs.

All of these factors, consumer acceptance, management's liability, the high cost of correcting poor conditions, etc. point very logically to the necessity of a well organized sanitation self-inspection program in every food plant, actively supported by the management.

These, however, are not the only reasons why such a program is desirable. The sanitary sciences as applied to food manufacture and preservation are broad in scope and are applicable from the raw material to delivery to the final consumer. It is closely tied directly and indirectly with production and quality. A division into several categories will illustrate this relationship.

Control of significant microorganisms is a problem familiar to most food technologists. If control is not adequate, microorganisms may cause a lowering of product quality, recognizable incipient spoilage, and sometimes spoilage after processing. In canning, for example, recontamination may occur from high microbial populations in can cooling water, or spoilage may develop from organisms of a heat resistant type which may multiply in the equipment. Slime and mold on equipment and building structures may affect the quality of the product and lower production efficiency. For example a slipping belt caused by slime growth can throw a high speed production line out of time. Acid producing microorganisms on equipment and in concrete floors may greatly accelerate corrosion.

Germicidal materials and methods of their application must be such that equipment will not be damaged and off flavors will not result. In some plants the continuous application of a germicidal solution of chlorine using the breakpoint method to give a chlorine residual in almost all of the plant water is a standard procedure. It is not a "cure-all," and does not eliminate the necessity for cleanup, but it does reduce slime growths and the buildup of microorganisms in equipment. It results in a cleaner plant and a better place to work, reduces equipment corrosion from bacterial causes, increases efficiency, and reduces the time and cost of keeping the plant clean. The last can be an important item if the additional time can be devoted to production.

In cleaning the plant a great deal of time and money can be wasted if the program is not properly organized. A study should be made of the cleaning job to eliminate lost motion. The most advantageous use of detergents, how they can be applied most effectively, where other cleaning aids such as high pressure water, special brushes, etc., can be used, where germicides should be applied, and by no means the least important, what degree of cleanliness is necessary in the various equipment are all important. Plant cleaning is an important labor cost item and quality factor because a dirty plant seldom produces a clean product, and clean equipment will not break down as often as dirty equipment.

Construction of equipment and buildings is of fundamental importance. How often is new equipment purchased or built without any consideration as to whether it can be taken apart for cleaning or can be cleaned at all? How often is it so located in the plant that it cannot be reached for cleaning? The cost of a piece of equipment, on a unit of production basis, is its original cost plus the expense of maintenance and cleaning during its entire useful life. Therefore, equipment purchased or built with sanitation and ease of cleaning in mind will be more economical to keep in a sanitary condition and significant savings will result. Quality losses and spoilage have, on many occasions, been traced to poorly designed and improperly constructed equipment.

Water is one of the commonest materials used in food plants. It serves as a packing medium for many products; it is used for fluming foods and waste materials; and serves for cooling, heating (steam), cleaning and drinking purposes. Certain chemicals in water have a bad effect on some products, on boilers and on various other equipment. The hardness of the water and type of hardness will govern, to a certain extent, the type of cleaning compounds that can be used without depositing chemical scale on equipment. The water must be bacteriologically safe and esthetically satisfactory for drinking and for use on the product. In the face of water shortages, it may be necessary to devise ways of saving water and reusing it for various purposes which raises many problems in determining where certain waters can be safely reused. The use of water greatly affects the problems of disposing of liquid or semi-liquid plant wastes. This is becoming increasingly important because much attention is now being given to reducing pollution so as to obtain the most economical and beneficial use of our natural waters for the greatest number of people. Many plants are having to re-evaluate their production of waste and means of its disposal. Solid wastes present disposal problems in some areas and the sanitary handling of wastes within the plant is of

importance in order that insect breeding and other insanitation are not encouraged.

Rats, mice, other animals and birds, living, breeding and feeding in a plant, may be the sources of serious contamination. The same is true of various insects such as houseflies, vinegar flies, cockroaches and the stored product insects. Much of the insect contamination of some products originates in the field, but even with complete elimination of the field problem, failure to consider the warehouse and the plant may be disastrous. There is no tolerance for filth, such as rodent droppings, rodent hair, bird droppings or feather barbules, so nothing short of perfection is acceptable.

Good housekeeping is tidiness and freedom from refuse in all areas. The care with which the workers perform their jobs is usually commensurate with the level of housekeeping in their working environment. Good or bad housekeeping is contagious and is generally the barometer of plant sanitation and also of quality and production efficiency. Visitors and inspectors usually obtain their first and sometimes lasting impression from the plant housekeeping. Safety inspectors always consider housekeeping of prime importance and fire insurance ratings are determined in part by the housekeeping in the plant. The mere presence of debris may in itself be the cause of contamination with foreign material or may harbor insects and rodents and contamination may result.

The employees' health, welfare and mental attitude are of great importance. It is expensive to hire new and untrained people. Much of an employee's time is spent in his working environment, and if we want to keep him healthy, happy and efficient, we should provide comfortable, clean, and sanitary facilities for his personal service. Clean toilets, locker rooms, rest rooms, warm water for washing, elimination of work hazards, etc., are of more immediate and personal interest to the individual worker than the plant production record or profit for the year.

More and more plants are providing cafeterias where the employees can obtain nutritious, wholesome meals at reasonable cost. Most plants believe this is a valuable service to the workers and results in greater efficiency. A poorly operated, insanitary cafeteria can result in many workers being incapacitated in a matter of hours due to food poisoning and food infections from eating various types of improperly prepared or stored foods. Such an unfortunate occurrence could close a plant because most of the crew would be stricken within a short period of time.

There are many details to be constantly watched in a preventive sanitation program, but the benefits are manifold. Some of these details will be raw product, production and quality control problems and in many plants the quality control man is also responsible for sanitation. The important thing is that all of these many details be given adequate and constant attention. Even though the manager is ultimately responsible he must assign this responsibility for sanitation details in the plant because he seldom has the necessary time to devote to them. It is only through a good self-inspection program that sanitation can be given adequate attention, the benefits gained and the troubles avoided. Government inspectors will usually give every possible consideration to the plant that is making an honest and effective effort to maintain proper sanitary conditions.

The organization of a self-inspection program and how to make a sanitation inspection are outlined in the new book, "Sanitation for the Food-Preservation Industries."[3] Every food plant manager and food technologist should read this book and have a copy available for ready reference. Assistance can also be obtained from many of the food industry associations and from private sanitation consulting firms.

Many plants and companies now have a self-inspection sanitation program and are benefiting materially. For the canning industry the National Canners Association has an industry-wide sanitation consulting and educational program centered in the sanitation departments of the research laboratories in Berkeley, California, and Washington, D. C. Almost from the inception of N. C. A. in 1907 sanitation was recognized as important to canning technology and a set of sanitary requirements was recommended at the 1914 convention of the Association and a sanitary code adopted in 1923. For nearly 35 years sanitation has been an important consideration in the determination of proper cooks to safeguard the health of the consumer. However, because of changing sanitation concepts, a "spot" survey was made for the industry of representative plants operating in January of 1945. The survey indicated that in every plant visited environmental conditions were imperfect from a critical modern sanitation viewpoint, and that managements were not fully aware of the fact.

The N. C. A. laboratories were immediately authorized to conduct an educational campaign on a national scale in order to promote a modern sanitation program for the entire industry regardless of membership in N. C. A.

A great many detailed, critical, voluntary and confidential sanitation surveys were made in canneries. It soon became obvious that a self-inspection program in each plant was the logical way to maintain proper conditions. It is necessary to recognize the possibility of the occurrence of product contamination and insanitary conditions. Constant and continuing vigilance to prevent trouble from developing is good business. Also the plant itself is best able to plan long range improvements. This meant that someone had to be given this responsibility in each plant. There were not enough trained people available, however, and it is not practical for every seasonal plant to add such a person to the permanent staff. In 1945 the N. C. A. sponsored one training course at the University of California, and since then has given seven additional training courses to train selected plant personnel to assume the responsibility for the plant self-inspection program.

Self-inspection is not a new or novel idea. Every plant has its supervisors and foremen of production who are responsible for production efficiency. Most plants also have quality control people who are responsible for product quality. Is it not logical to expand this idea to include quality of the production and working environment as an aid to both production and quality control? Experience has amply demonstrated that such a program should be established and that all functions should be properly coordinated.

Production speed up and unexpected shifts to around-the-clock production operations should not be attempted without also re-evaluating and intensifying the sanitation part of the plant operations. Necessary budget cuts should not emasculate the sanitation self-inspection program as sometimes happens when management mistakenly regards it as an unnecessary refinement. If the program has been operated efficiently and the value demonstrated, intelligent management will hesitate to cut it unduly.

The alternative means of control, and control there must be, is through official inspection and enlarged inspection forces. This will increase the burden on industry and require higher expenditures for corrective measures often at a critical time for the plant. It would merely serve to maintain minimum standards for those things specifically covered by the laws and regulations and point out trouble after it has occurred rather than employing preventive measures in the first place. Official inspection is of value, however, in disclosing conditions that have been inadvertently overlooked and in keeping the infrequent recalcitrant individual, who refuses to recognize his responsibilities from threatening the reputation of the rest of the industry. It is far better that management accept their responsibilities to the public and recognize sanitation in its true relationship to the entire operation. From consideration of the consumer's interest, common decency, personal pride and plant economics, good sanitation is one of industry's best investments. Self-inspection or self-policing is the sensible approach and in the American tradition of free enterprise.

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